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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,581	04/07/2004	Mark E. Deem	17315-002002	8576

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,581

Applicant(s)

DEEM ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/29/04, 10/25/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS dated 9/21/05 and 11/14/05.</u> |

DETAILED ACTION

Information Disclosure Statement

1. The foreign patents and other documents listed on pages 1-4 in the information disclosure statement filed on September 21, 2005 have not been considered. The other documents listed were not available and need to be refiled.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. **Claims 1, 4, 6-10 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Oz, et al. (US Patent Number 6,269,819).**

5. Regarding Claim 1, Oz'819 discloses a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8,

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lines 19-21) having a fastener releasably attached (column 2, lines 47-54). The fastener is deployed to hold the leaflets of the heart valve together and reduce regurgitation (column 2, lines 47-54).

6. Regarding Claim 4, Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

7. Regarding Claim 6 and 8, Oz'819 discloses that the fastener clips will be made out of nitinol, stainless steel or titanium, which are not bioabsorbable materials, so they will be in place permanently (column 5, lines 14-17). Furthermore, since there are only two leaflets in some valves, it is inherent that the fastener will be holding opposed leaflets. Further regarding Claim 8, it is known that chordae are part of the leaflets, therefore, the opposed chordae are linked when the opposed leaflets are attached.

8. Regarding Claim 7 and 9, Oz'819 discloses that clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

9. Regarding Claim 10, Oz'819 discloses advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30).

10. Claim 21 is rejected under 35 U.S.C. 102(a) as being anticipated by Oz'819.

11. Regarding Claim 21, Oz'819 discloses the use of a annular ring to reduce regurgitation, which occurs by changing the shape of the valve, and then using suture to fasten the leaflets of a valve to further reduce regurgitation (column 10, lines 4-7).

Claim Rejections - 35 USC § 103

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12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 2, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 1, and in further view of Campbell, et al. (US Patent Number 6,143,024).**

15. Regarding Claims 2, 3 and 5, Oz'819 teaches the limitations of Claim 1. Oz'819 does not teach the use of a ring that shortens the annulus. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22).

Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

16. **Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819 in view of Campbell'024.**

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17. Regarding Claim 11, Oz'819 teaches a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21).

18. Regarding Claim 12, 14 and 16, Oz'819 teaches the use of fastener clips to clip the leaflets of a valve together (column 6, lines 23-28) to reduce regurgitation. Further regarding Claim 14, it is known that chordae and papillary muscles are part of the leaflets, therefore, the opposed chordae and opposed papillary muscles are linked when the opposed leaflets are attached.

19. Regarding Claim 13 and 15, Oz'819 teaches that a clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

20. Regarding Claim 18, Oz'819 teaches that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

21. Regarding Claim 20, Oz'819 teaches advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30).

22. Regarding Claim 11, Oz'819 does not teach the use of a releasably attached annuloplasty device that is implanted. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

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23. Regarding Claim 17, Oz'819 does not teach shortening the annulus.

Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

24. Regarding Claim 19, Oz'819 does not teach tightening the annulus.

Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

25. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 21, and in further view of Campbell'024.

26. Oz'819 teaches the limitations of Claim 21, as described above. Regarding Claim 22, Oz'819 also teaches a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21).

27. Regarding Claim 24, Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

28. Regarding Claim 26, Oz'819 discloses that clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

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29. Regarding Claim 22, Oz'819 does not teach the use of a releasably attached annuloplasty device that is implanted. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

30. Regarding Claim 23 and 25, Oz'819 does not teach the use of a ring that shortens or tightens the annulus. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

31. Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819 in view of Campbell'024.

32. Regarding Claim 27, Oz'819 teaches a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21).

33. Regarding Claim 30, Oz'819 teaches that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

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34. Regarding Claim 32 and 34, Oz'819 discloses that the fastener clips will be made out of nitinol, stainless steel or titanium, which are not bioabsorbable materials, so they will be in place permanently (column 5, lines 14-17). Furthermore, since there are only two leaflets in some valves, it is inherent that the fastener will be holding opposed leaflets. Further regarding Claim 34, it is known that chordae are part of the leaflets, therefore, the opposed chordae are linked when the opposed leaflets are attached.

35. Regarding Claim 33 and 35, Oz'819 discloses that clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

36. Regarding Claim 27 and 28, Oz'819 does not teach the use of a releasably attached annuloplasty device that is implanted. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

37. Regarding Claim 29, Oz'819 does not teach shortening the annulus. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

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38. Regarding Claim 31, Oz'819 does not teach tightening the annulus.

Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). Therefore it would have been obvious to one skilled in the art at the time of the invention to use a ring that surrounds the annulus in order to restore the natural size and shape of the annulus to restore normal function.

Conclusion

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

40. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

41. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Imb

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
PRIMARY EXAMINER